

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN**

JILL WHITCOMB,

Plaintiff,

vs.

Civil Action No. _____

SYLVIA BURWELL, in her official capacity as
Secretary, U.S. Department of Health and Human Services,

Defendant.

COMPLAINT

NOW COMES the Plaintiff, Jill Whitcomb, by her attorneys, Parrish Law Offices and McNally Peterson, S.C., for judicial review of the final agency decisions of Defendant, Sylvia Burwell, in her official capacity as Secretary of the U.S. Department of Health and Human Services, and alleges and shows to the Court as follows:

Preliminary Statement

1. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§1395, *et seq.* (“the Medicare Act”), and 42 U.S.C. §405(g). Plaintiff, Jill Whitcomb, seeks judicial review of a final decision of Defendant, Sylvia Burwell, in her official capacity as the Secretary (“the Secretary”) of the U.S. Department of Health and Human Services (“HHS”), denying Medicare payment for claims relating to a continuous glucose monitoring system.

2. Ms. Whitcomb has had Type I diabetes for 35 years, and, despite being consistently conscientious, following nutritional instructions, regularly exercising, performing frequent self-monitoring (six or more times daily) and following a comprehensive insulin

administration regimen for her diabetes, her glucose levels still remain uncontrolled, *i.e.*, “brittle.”

3. Nationally and internationally, continuous glucose monitoring is recognized as the standard of care for brittle diabetes.

4. A National Coverage Determination (“NCD”) is a determination regarding coverage that exists nationally.

5. NCD 40.2 provides Medicare coverage for home blood glucose monitors for diabetics who are Medicare beneficiaries.

6. NCD 280.1 provides Medicare coverage for durable medical equipment (“DME”).

7. In 2008, National Government Services (“NGS”) issued a local coverage determination (“LCD”) L27231, indicating that blood glucose monitors and related accessories and supplies, would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient’s physician states the patient is capable of using the device; and (3) the device is designed for home rather than clinical use.

8. The NGS LCD did not indicate that a continuous glucose monitor (“CGM”) was not covered.

9. An NGS informal communication known as an “Article” states that NGS considers a CGM to be “precautionary.”

10. Medicare Advantage Organizations (“MAOs”) are required to cover at least those medical devices and supplies covered by Medicare.

11. Consistent with the determination of most commercial insurance companies, United Healthcare of Wisconsin, Inc., issued a policy indicating that it generally covers CGMs

under the durable medical equipment (“DME”) benefit, deeming them to be reasonable and medically necessary for individuals suffering from brittle diabetes.

12. The denial at issue in this action first arose when the Secretary, acting through a Medicare Advantage Organization, United Healthcare of Wisconsin, Inc./Secure Horizons (“United Healthcare”), unlawfully denied claims for payment from Medicare for the Plaintiff’s CGM.

13. Ms. Whitcomb appealed that denial through the multi-step Medicare Part B appeals process.

14. After a hearing, Administrative Law Judge Richard Bush found that coverage was consistent with the NCD 40.2 and LCD L27231, deemed the CGM to be reasonable and medically necessary, and ordered United Healthcare to cover the CGM for Ms. Whitcomb. The ALJ specifically declined to follow the informal Article, noting the various emergency visits, hospital records and other medical records supported her need for CGM.

15. United Healthcare appealed, and the Medicare Appeals Council (“Appeals Council”) reversed the ALJ’s decision and denied the CGM claims at issue on the grounds that “the record was insufficient to depart from the coverage standards in the LCD and policy article.” It took Ms. Whitcomb over 18 months to exhaust the administrative process the first time.

16. Ms. Whitcomb appealed the denial to this Court which, on May 26, 2015, vacated the Appeals Council’s determination, stating that its application of the Article was improper, and remanded the case back to the Secretary to determine “whether a continuous glucose monitor is reasonable and medically necessary for [Ms.] Whitcomb and not otherwise excluded” from Medicare coverage. *See* Case No. 2:13-CV-00990-WED, Dkt. 51, Decision and Order at 9.

17. Rather than issuing a decision consistent with the Court's remand instruction, the Appeals Council remanded the case to the ALJ to determine whether a CGM meets the Medicare definition of DME, whether it falls within the Medicare statutory benefit of DME, whether the Article is binding guidance for the United Healthcare plan, and whether it is reasonable and medically necessary for Ms. Whitcomb.

18. On October 14, 2015, the ALJ issued a second, fully favorable decision for Ms. Whitcomb.

19. The ALJ found that a CGM meets the Medicare definition of DME, a CGM is eligible for Medicare coverage under the DME benefit, and it is reasonable and medically necessary for Ms. Whitcomb to manage her brittle diabetes.

20. United Healthcare appealed the ALJ's October 14, 2015 favorable decision to the Appeals Council.

21. The Medicare regulations and statute require the Appeals Council to issue a decision within 90 days of an appeal.

22. The Appeals Council did not render a decision until November 8, 2016, again denying coverage of a CGM and asserting that a CGM does not serve a medical purpose, but is simply precautionary, and, therefore, not covered under Medicare's DME benefit.

23. The Appeals Council ignored an April 2016 ruling by the HHS Civil Remedies Division which found that CMS' "long-standing policy of broadly construing the DME benefits category is consistent with Congressional intent" and that "there is no peer-reviewed literature, medical opinions, or even any analysis from an individual with a medical background that supports a conclusion that CGM is never reasonable and necessary irrespective of the beneficiary's condition."

24. The Appeals Council also ignored the July 2016 recommendation by the U.S. FDA advisory panel that in view of the precision of current CGMs, patients do not have to confirm the CGM readings with a fingerstick before making insulin adjustments (which recommendation was adopted by the FDA in December 2016), and the September 2016 FDA approval of a “closed loop” system whereby the CGM communicates directly with an insulin pump to administer insulin without any intermediary testing.

25. The Appeals Council further ignored the consensus of medical experts and societies, the peer-reviewed literature, and the independent government technology assessment, which acknowledge CGM as reasonable and medically necessary for individuals suffering from brittle Type 1 diabetes with hypoglycemic unawareness – indeed a CGM is recognized as the primary and essential medical device for such individuals to control their diabetes.

26. Plaintiff seeks an order reversing this coverage denial and instructing the Secretary to cover the CGM claims at issue in accordance with applicable law. The Secretary’s decision at issue is arbitrary and capricious, not supported by the evidence or Medicare law, regulation or guidance, and is inconsistent with the medical records and the standard of care.

Jurisdiction and Venue

27. The Court has subject matter jurisdiction under 42 U.S.C. §§405(g) and 1395ff(b) (appeal of final Medicare program agency decision) and under 28 U.S.C. §§1331 (federal question) and 1361 (mandamus).

28. Venue lies in this judicial district under 42 U.S.C. §§405(g) and 1395ff(b) and 28 U.S.C. §1391(e).

Parties

29. Jill Whitcomb is a Medicare beneficiary residing at 1442 Oriole Drive, Hartford, WI 53027 who is seeking Medicare coverage of her claims for a CGM.

30. Ms. Whitcomb has been a Medicare beneficiary since July 1, 2007.

31. Plaintiff brings this action, which is an appeal of the Secretary's final decision denying Medicare claims for a CGM.

32. Defendant, Sylvia Burwell, is the Secretary of HHS, the Federal department which contains the Centers for Medicare & Medicaid Services ("CMS"). The Secretary, the Federal official responsible for administering the Medicare Program, has delegated that responsibility to CMS.

Factual Background

General Background of the Medicare Program

33. The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals afflicted with end-stage renal disease. 42 U.S.C. §§1395 -1395ccc; 42 C.F.R. Parts 400 – 1004. Medicare includes Parts A through D. This action arises under Part B (covering basic non-hospital medical needs) and Part C (relating to Medicare Advantage Organizations).

34. Under 42 U.S.C. §1395hh(a)(1), the Secretary is required to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program. That statute also states:

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. §1395hh(a)(2).

35. The Secretary has elected to publish many rules implementing the Medicare program in various manuals, such as the Medicare Program Integrity Manual (“MPIM”) and the Medicare Claims Processing Manual (“MCPM”). However, under 42 U.S.C. §1395hh(a)(2), these manual provisions, which are not promulgated in accordance with the notice and comment provisions of the APA, are not effective to the extent that any of them “establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits” under Medicare.

Medicare Coverage and Payment of DMEPOS

36. Medicare Part B provides for coverage and payment for “medical and other health services,” which includes durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”) provided to Medicare beneficiaries. 42 U.S.C. §§1395k(a) and 1395x(n) and (s). To be paid by Medicare, medical devices and supplies must be found to be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. §1395y(a).

37. Consistent with Congressional intent, CMS has a long-standing policy of construing the DME benefit category broadly.

38. DMEPOS is categorized by CMS pursuant to the Healthcare Common Procedure Coding System (“HCPCS”) and is assigned an alpha-numeric code consisting of a letter and a four-digit number. Some items of DMEPOS are assigned a unique HCPCS code. To obtain a unique code, a medical device or supply must have achieved sufficient volume, *i.e.*, adoption within the medical community. www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/

decisiontree.pdf.

39. Claims for Medicare payment for DMEPOS items supplied to Medicare beneficiaries are presented to DME Medicare Administrative Contractors (“DMACs”). DMACs adjudicate these claims as agents of the Secretary pursuant to contracts with her. The country is divided into four geographic jurisdictions, each of which has its own DMAC. A DMEPOS supplier must submit each of its claims to the DMAC having jurisdiction for reimbursement of that claim. 42 C.F.R. §424.32.

40. After a claim has been submitted to the appropriate DMAC, the DMAC must determine if the item is covered or otherwise reimbursable under the Medicare Act, determine any payment due and make that payment accordingly, and notify the parties of the determination. 42 C.F.R. §405.920. For DMEPOS, payment is 80% of the actual charge or a fee schedule amount where a fee schedule has been created in accordance with 42 C.F.R. §§ 414.220 through 414.232. *See* 42 C.F.R §414.210.

Medicare Coverage and Glucose Monitoring

41. A National Coverage Determination (“NCD”) is “a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.” 42 C.F.R. §405.1060(a)(1).

42. An NCD is binding on all Medicare contractors, including administrative law judges (“ALJs”) and the Medicare Appeals Council (“Appeals Council”). 42 C.F.R. §405.1060(a)(4).

43. NCD 280.1 defines DME as equipment which: (a) can withstand repeated use; (b) is primarily and customarily used to serve a medical purpose; (c) generally is not useful to a person in the absence of illness or injury; and (d) is appropriate for use in the patient’s home.

44. To ensure coverage of diabetic testing equipment and supplies, in 2006, the Secretary issued the current effective version of the NCD providing Medicare coverage for blood glucose monitors. *See* Medicare National Coverage Determinations Manual §40.2, Home Blood Glucose Monitors (hereinafter “NCD 40.2”).

45. Under NCD 40.2, a home blood glucose monitor is covered when: (a) the patient has been diagnosed as having diabetes; (b) the patient’s physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner; and (c) the device is designed for home rather than clinical use. *Id.*

46. The NCD does not distinguish between single-use home glucose monitors or continuous-use glucose monitors.

47. In addition to an NCD, MACs, including DMACs, can issue local coverage determinations (“LCDs”).

48. LCDs are issued after consideration of the peer-reviewed literature, consultation with the relevant medical community, notice and comment. *See* MPIM Ch. 13, §13.7.

49. When an ALJ is rendering a decision, although not bound by an LCD, an ALJ must give deference to an LCD. 42 C.F.R. §405.1062. If an ALJ does not give deference to an LCD, the ALJ must explain why he or she did not.

50. In 2008, National Government Services (“NGS”) issued LCD L27231 indicating that blood glucose monitors and related accessories and supplies would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient’s physician states the patient is capable of using the device; and (3) the device is designed for home rather than clinical use.

51. The NGS LCD did and does not indicate that a CGM was and is not covered.

52. Articles, which are informal communications issued by MACs, may be issued without consultation with the relevant medical community or the peer-reviewed literature, are not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the qualified independent contractor (“QIC”) or ALJ. 42 C.F.R. §405.1062.

53. MAOs are required to offer their enrollees, at a minimum, all basic Medicare covered services. *See* 42 C.F.R. §422.101.

54. MAOs must comply with NCDs and LCDs. *Id.*

55. The United Healthcare Evidence of Coverage document explicitly states that it covers diabetes self-monitoring training, nutrition therapy, and supplies, including “coverage for glucose monitors.”

The Process for Appeals of Medicare Claims Decisions

56. Congress has established a five-step process for a Medicare beneficiary, such as Ms. Whitcomb, to follow to obtain judicial review when she is dissatisfied with the initial determination of a claim by the DMAC. The first step in the process is a request for redetermination by the DMAC. *See* 42 C.F.R. §§405.940 through 405.958.

57. Upon a request for redetermination, the DMAC is required to adjudicate a claim and render a decision based on the evidence in the record. 42 C.F.R. §405.954. Under 42 C.F.R. §405.956(b), the redetermination notice issued by the DMAC must include, *inter alia*, a summary of the evidence used in making the redetermination, an explanation of relevant laws, regulations, coverage rules, and CMS policies that apply to the case and a summary of the rationale for the redetermination in clear, understandable language. 42 C.F.R. §405.956(b).

58. A Medicare beneficiary who is dissatisfied with a DMAC’s redetermination decision may request reconsideration by the DME QIC. 42 C.F.R. §405.960. The QIC is

required to review the record of the claims and issue a reconsideration decision having the same decision elements as the DMAC's redetermination decision. 42 C.F.R. §405.976(b).

59. A Medicare beneficiary may appeal the QIC reconsideration decision by requesting a hearing before an ALJ. 42 C.F.R. §405.1000.

60. ALJs are bound to follow an NCD. 42 C.F.R. §405.1060(a)(4).

61. In contrast to an NCD, LCDs issued by MACs, including DMACs, are not binding on an ALJ. 42 C.F.R. §405.1062(a).

62. When the ALJ is rendering a decision, although not bound by an LCD, if an ALJ applies an LCD, the ALJ must apply the LCD in place on the date the item or service was provided. 42 C.F.R. §405.1034.

63. After an ALJ issues a decision, the Appeals Council may decide on its own motion to review a decision by an ALJ. *See* 42 C.F.R. §405.1110. An MAO also may appeal a case to the Appeals Council for it to consider reviewing.

64. Under BIPA, the Appeals Council must render a decision within 90 days of an appeal.

65. If the Appeals Council does not render a decision within 90 days of an appeal, an appellant can request that the case be escalated to District Court. 42 C.F.R. §405.1130.

66. An NCD is binding on the Appeals Council, and the Appeals Council limits its review to the evidence contained in the record before the ALJ. 42 C.F.R. §405.1122(a)(1).

67. The Appeals Council's decision becomes the Secretary's decision and is the final agency decision for purposes of judicial review. 42 C.F.R. §405.1136(d).

68. A Medicare beneficiary seeking judicial review of the Secretary's final decision may file a complaint "in the district court of the United States for the judicial district in which

the party resides or where such individual, institution, or agency has its principal place of business.” 42 C.F.R. §405.1136; *see also* 42 U.S.C. §§405(g) and 1395ff(b). Timely judicial review is being sought for a decision rendered by the Secretary. 42 C.F.R. §405.1130 and §405.1134.

Statement of Facts and Prior Proceedings

Continuous Glucose Monitoring and Brittle Diabetes

69. Unfortunately, despite consistently conscientiously following nutritional instructions, regularly exercising, performing frequent self-monitoring (six or more times daily), and following a comprehensive insulin administration regimen for their diabetes, some individuals still have uncontrolled glucose levels. Such diabetes is known as “brittle diabetes.”

70. Some individuals with diabetes suffer from hypoglycemic unawareness, *i.e.*, they are unaware of an impending, dangerous low drop in blood glucose. Hypoglycemic unawareness may result in prolonged and profound exposure to hypoglycemia, resulting in seizure, loss of consciousness and brain damage.

71. Individuals suffering from brittle diabetes often have frequent nighttime hypoglycemic episodes which causes a progressive loss of mental function.

72. It is estimated that an undetected nighttime low results in the death of approximately one out of every 20 individuals suffering from Type 1 diabetes each year.

73. A CGM alerts individuals suffering from brittle diabetes of both hypo- and hyperglycemic episodes which can occur at a frequency that would confound any attempt to manage through simple finger blood glucose checks.

74. A CGM operates by measuring the interstitial fluid under the skin which consistently tracks with and reflects the glucose concentration in the blood.

75. A CGM enables patients to manage their diabetes on an immediate basis and provides information to enable a clinician to better manage diabetes on a long-term basis.

76. A CGM has been recognized as the standard of care for brittle diabetics, not only within the United States, but internationally. *See* the consensus statements/guidelines of the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring, at 3 (which has recommended CGM since at least 2007); the American Diabetes Association at S21-S22 (which has included it in its recommendation since at least 2009); the Endocrine Society (which recently updated its statement to recommend CGM for all Type 1 diabetics and not just those with hypoglycemic unawareness); the German Diabetes Association (which reviews the favorable consensus statements of many European nations); various French Endocrinology and Diabetic Societies at S76-77; the European Society for Pediatric Endocrinology, the Pediatric Endocrine Society and the International Society for Pediatric and Adolescent Diabetes at 4-5, 11.

77. The consensus of medical opinion on the safety and effectiveness of CGM for brittle diabetes is supported by at least nine peer-review publications reflecting randomized, controlled clinical trials.

78. Based on the consensus statements, peer-reviewed literature and widespread acceptance of CGM for brittle diabetics, more than 98% of commercial insurers cover CGM.

79. A Federally funded technology assessment found CGM reasonable and medically necessary for brittle diabetics. *See* the Agency for Health Care Research and Quality (“AHRQ”) report of 2010 (AHRQ at 102-103, 105).

80. In July 2016, an FDA advisory panel recommended that the FDA label for Dexcom's CGM system be revised to not require confirmatory fingersticks before making insulin adjustments.

81. In September 2016, in view of the precision of current CGMs in measuring blood glucose levels, the FDA approved a closed-loop insulin system wherein a CGM directly communicates with an insulin pump to administer insulin without a confirmatory fingerstick.

82. In December 2016, the FDA revised the labelling for a CGM device indicating that confirmatory fingersticks are not required before making insulin adjustments based on CGM readings.

The Proceedings Below Relating to the Claims at Issue in this Action

83. This is an action for judicial review of final administrative decision of the Secretary with the Appeals Council's Appeal Number 1-1012671541R2, M-16-9431 (issued November 8, 2016).

84. Ms. Whitcomb has had Type 1 diabetes for over 35 years.

85. Despite frequent testing (an average of 10 times daily), she was unable to gain control of her diabetes and has been forced into disability. She also suffers from hypoglycemia unawareness and gastroparesis.

86. Because of her hypoglycemia, Ms. Whitcomb has repeatedly lost consciousness, been hospitalized and taken to the emergency room. Accordingly, on April 14, 2011, her healthcare provider prescribed her a CGM which checks Ms. Whitcomb's glucose approximately 288 times a day and alerts her when she is experiencing a hypoglycemic event.

87. Ms. Whitcomb's healthcare provider signed a statement of medical necessity attesting that the CGM was and is reasonable and medically necessary for Ms. Whitcomb. With

CGM, Ms. Whitcomb had a “vast” clinical improvement of her blood glucose level control. In the first month of using the CGM, she experienced only six hypoglycemic events compared to the 22 events in the preceding month when she did not have a CGM.

88. Ms. Whitcomb filed a claim for the CGM and related supplies which were denied by United Healthcare, although United Healthcare stated it understood how CGM “might be helpful for [Ms. Whitcomb].”

89. Ms. Whitcomb appealed the denial through the administrative process.

90. Hearings were conducted on October 15, 2012 and January 17, 2013. During the January 17, 2013 hearing, Ms. Whitcomb’s healthcare provider testified that CGM is considered the standard of care for Type 1 diabetics with hypoglycemic unawareness and is supported by peer-reviewed literature. She noted Ms. Whitcomb’s dire need for CGM to control her diabetes.

91. Ms. Whitcomb’s healthcare provider testified that CGM was “precautionary” solely to the extent that it prevented hypoglycemic and hyperglycemic events and premature death. On February 6, 2013, Administrative Law Judge Bush rendered a Fully Favorable Decision finding that Medicare coverage of CGM is consistent with the NCD and LCD, and that the CGM was reasonable and medically necessary for Ms. Whitcomb.

92. The ALJ found that neither the NCD nor LCD distinguished glucose monitors and continuous glucose monitors and that Ms. Whitcomb satisfied the coverage criteria of NCD 40.2 and LCD L27231.

93. The ALJ did not give the Article deference because Ms. Whitcomb had demonstrated her dire medical need for CGM based on her uncontrolled diabetes that had resulted in emergency room visits.

94. The ALJ's decision was and is consistent with the decisions of more than 30 Medicare ALJs who have considered this issue for other Medicare beneficiaries and approved claims before and after the claim at issue in this case.

95. On March 1, 2013, United Healthcare appealed the favorable ALJ decision to the Appeals Council.

96. On August 23, 2013, the Appeals Council reversed the Fully Favorable ALJ Decision and found that CGM was not covered based on a statement in an Article that stated CGM was "precautionary."

97. The Secretary found that "the [administrative] record was insufficient to depart from the coverage standards in the LCD and policy article."

98. Ms. Whitcomb appealed the matter to this Court which found that the Secretary's application of Article A47238 was in error and remanded the matter back "to determine whether a continuous glucose monitor is reasonable and necessary for Whitcomb and not otherwise excluded."

99. Although the Appeals Council could have decided the case in a manner consistent with the Court's remand, after the matter had been pending at the Appeals Council level more than 90 days, it chose to remand the matter back to the ALJ level to determine whether a CGM falls within the DME statutory benefit.

100. The ALJ conducted a new hearing and determined that CGM systems meet the definition of DME. The ALJ considered each required element of under NCD 280.1 and found that the CGM satisfied each of these requirements. The ALJ issued a second fully favorable decision on October 14, 2015.

101. On December 10, 2015, ignoring its own policy that recognizes that a CGM is DME that is reasonable and medically necessary for individuals suffering from Type 1 diabetes, United Healthcare appealed to the Appeals Council, again stating a CGM is simply a secondary warning system.

102. After the matter had been pending more than 90 days, in view of Ms. Whitcomb's critical need for the CGM, she attempted to escalate the matter to District Court. The Appeals Council denied her request and did not issue a decision until November 8, 2016.

103. The Appeals Council reversed the ALJ's favorable decision finding that "CGM systems . . . do not have a primary medical purpose because they are precautionary items." The Appeals Council reasoned that because Ms. Whitcomb "must still use another device to accomplish the medical purpose at issue, the device is essentially used as an added precaution, but not for a primary medical purpose."

104. The Appeals Council ignored an April 2016 decision by the HHS Civil Remedies Division that found that the statement that CGM is precautionary is not supported by substantial evidence and is invalid under the reasonableness standard.

105. The Appeals Council also ignored the developments at the FDA that are premised on the current CGMs being so precise that fingerstick confirmations are no longer necessary.

106. The Appeals Council cited no evidence or regulation in support of its argument that a CGM is not DME.

COUNT 1:

PLAINTIFF'S CONTINUOUS GLUCOSE MONITOR IS USED PRIMARILY FOR A MEDICAL PURPOSE

107. The Plaintiff re-alleges and reiterates the allegations contained in paragraph Nos. 1 through 106 of the Complaint as if set forth fully herein.

108. Under the Medicare statute, 42 C.F.R. §1395ff(b), the final agency decision included in this action is subject to judicial review under the applicable provisions of the APA. Under the APA, the reviewing court shall set aside the final agency decision if, *inter alia*, it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

109. To the extent that the Secretary's decision in this action found that CGM is not used primarily for a medical purpose and, therefore, not reasonable and medically necessary, the Secretary's decision must be set aside because it is contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

110. CGM is recognized, nationally and internationally, as the medical standard of care and reasonable and medically necessary for the management of brittle Type 1 diabetes and hypoglycemic unawareness. The CGM's essential medical purpose is recognized throughout the peer-reviewed literature, professional standards and the payer community.

111. Based on the foregoing, the Secretary's decision that the CGM is not used primarily for a medical purpose, is contrary to Medicare regulations, arbitrary and capricious, and unsupported by substantial evidence in the record, and Plaintiff asks the Court to reverse the Secretary's decisions and issue an order finding that the CGM is primarily used for a medical purpose and is reasonable and medically necessary, and direct the Secretary to make appropriate payment for the device.

COUNT 2:

PLAINTIFF'S CONTINUOUS GLUCOSE MONITOR IS COVERED UNDER NCD 280.1

112. The Plaintiff re-alleges and reiterates the allegations contained in paragraph Nos. 1 through 111 of the Complaint as if set forth fully herein.

113. The Secretary's decision in this action must be set aside because it is arbitrary, capricious, and unsupported by substantial evidence in the record. The finding that a CGM does not meeting the definition of DME and, therefore, is not covered under the DME statutory benefit is contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

114. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is DME and eligible for Medicare coverage under the DME statutory benefit.

COUNT 3:

THE SECRETARY FAILED TO FOLLOW NCD 280.1

115. The Plaintiff re-alleges and reiterates the allegations contained in paragraph Nos. 1 through 114 of the Complaint as if set forth fully herein.

116. To the extent that the Secretary's decision is premised on its failure to apply NCD 280.1, the Secretary's decision must be set aside because it is contrary to law, arbitrary and capricious and without observance of procedure required by law. 42 C.F.R. §405.1060(a)(4).

COUNT 3:

THE SECRETARY FAILED TO RENDER A TIMELY DECISION

117. The Plaintiff re-alleges and reiterates the allegations contained in paragraph Nos. 1 through 116 of the Complaint as if set forth fully herein.

118. The Secretary failed to render a decision within the statutory time period; therefore, the Secretary's decision must be set aside because it is contrary to law, arbitrary and capricious and without observance of procedure required by law. 42 C.F.R. §405.1060(a)(4).

COUNT 4:

**PLAINTIFF'S CONTINUOUS GLUCOSE MONITOR IS REASONABLE AND
MEDICALLY NECESSARY FOR HER BRITTLE TYPE 1 DIABETES**

119. The Plaintiff re-alleges and reiterates the allegations contained in paragraph Nos. 1 through 118 of the Complaint as if set forth fully herein.

120. The Secretary's decision in this action must be set aside because it is arbitrary, capricious, and unsupported by substantial evidence in the record. CGM is reasonable and medically necessary for individuals suffering from brittle Type 1 diabetes with hypoglycemic unawareness, including Ms. Whitcomb. The reasonableness and medical necessity of CGM for brittle Type 1 diabetes is supported by numerous peer-reviewed studies, professional society consensus statements, experts in the treatment of diabetes, and the payer community.

121. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary for individuals suffering from brittle Type 1 diabetes, including Ms. Whitcomb.

WHEREFORE, Plaintiff prays for judgment as follows:

A. For an order setting aside the November 8, 2016 Decision that Plaintiff's Medicare Advantage Plan is not required to provide coverage for Plaintiff's continuous glucose monitoring system;

B. For an order declaring that a continuous glucose monitoring system is, by definition, durable medical equipment and eligible for coverage by Plaintiff's Medicare Advantage Plus Plan under the NCD 280.1;

C. For an order remanding this action to the Secretary with instruction to authorize Plaintiff's Medicare Advantage Plan to provide coverage for Plaintiff's continuous glucose monitoring system;

D. For an order that this Court will retain jurisdiction over the decisions at issue herein until the Secretary's authorization of payment to Plaintiff's Medicare Advantage Plan is made and Plaintiff's claims for her continuous glucose monitoring system have been completed and will continue to be paid;

E. For an award of Plaintiff's legal fees, plus litigation expenses and costs, pursuant to the Equal Access to Justice Act, 28 U.S.C. §2412(d)(1)(A); and

F. For such other and further relief as this Court deems just and proper.

Dated: January 4, 2017

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